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May 10, 2022

VIA CM/ECF

Honorable Maryellen Noreika
J. Caleb Boggs Federal Building
844 N. King Street, Unit 19, Room 4324
Wilmington, DE 19801-3555

Re: Nippon Shinyaku Co. v. Sarepta Therapeutics, Inc., C.A. No. 1:21-cv-01015-MN

Dear Judge Noreika:

Pursuant to the Court’s May 5, 2022 Oral Order (D.I. 108), plaintiff/counter-defendant Nippon Shinyaku Co., Ltd. (“Nippon Shinyaku”) and defendant/counter-plaintiff Sarepta Therapeutics, Inc. (“Sarepta”) have met and conferred, but were unable to reach agreement on the form of preliminary injunction for entry by the Court. Nippon Shinyaku’s proposed order is attached hereto as Exhibit A, and Sarepta’s proposed order is attached hereto as Exhibit B. The parties disagree regarding the scope of the injunction that must be entered by the Court and have set forth the rationale regarding their respective proposals below.

Nippon Shinyaku’s Position:

Consistent with the Federal Circuit’s Judgment and Opinion (D.I. 92) and Mandate (D.I. 107), Nippon Shinyaku requests that this Court promptly enter an order requiring Sarepta to take the necessary steps at the Patent Trial and Appeal Board (“PTAB”) to withdraw Sarepta’s previously filed *inter partes* review petitions (“IPR Petitions”). Nippon Shinyaku also asks the Court to ensure Sarepta does not benefit from its impermissibly filed IPR Petitions by precluding Sarepta from referencing, making arguments, or presenting evidence regarding the IPR Petitions and related PTAB proceedings in connection with Sarepta’s invalidity counterclaims/defense in the instant action.

First, Sarepta’s request to stay its participation in the IPR proceedings (rather than withdraw the IPR Petitions) while it contemplates further appeal to the Supreme Court improperly ignores both the letter and spirit of the Federal Circuit’s Mandate. As this Court recognized, the Federal Circuit has remanded this case “for entry of a preliminary injunction.” (D.I. 108) And Nippon Shinyaku’s Motion for Preliminary Injunction sought an order requiring Sarepta to withdraw its IPR Petitions. (D.I. 25 at 10)

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Sarepta's proposal to provide incomplete relief subverts the Federal Circuit's Mandate, and thus cannot be entered by this Court. Under the "mandate rule," this Court "has no power or authority to deviate from the mandate issued by [the Federal Circuit]." *ArcelorMittal France v. AK Steel Corp.*, 786 F.3d 885, 888 (Fed. Cir. 2015) (quoting *Banks v. United States*, 741 F.3d 1268, 1276 (Fed. Cir. 2014)); *see also Briggs v. Pa. R. Co.*, 334 U.S. 304, 306 (1948) (same). Nippon Shinyaku moved for a preliminary injunction requiring Sarepta to withdraw its impermissibly filed IPR Petitions. The Federal Circuit's Mandate orders the entry of the requested injunction. (D.I. 92 at 4 ("Nippon Shinyaku filed a motion for a preliminary injunction asking the court . . . to require that Sarepta withdraw the petitions)). Sarepta could have sought to stay entry of the mandate at the Federal Circuit, but it chose not to. Accordingly, this Court should reject Sarepta's invitation to circumvent the Federal Circuit's Mandate.

Second, the Court should reject Sarepta's proposed order because it would compound the irreparable harm to Nippon Shinyaku by inviting further delay and the needless burden of litigating in multiple forums. Sarepta, in effect, invites the Court to ignore the preliminary injunction ruling and maintain the *post-suit* status quo—parallel litigation over IPR Petitions in a forum the Federal Circuit expressly held Sarepta "bargained away" (D.I. 92-1 at 15)—rather than restore the *pre-suit* status quo Nippon Shinyaku's motion sought. Sarepta's proposed order also ignores the realities of the PTAB proceedings. Nippon Shinyaku (and not Sarepta) will need to immediately take action if/when the PTAB lifts any stay of the IPR proceedings.¹ The next PTAB deadline is the patent owner's response from Nippon Shinyaku, which will require extensive attorney and expert time and expense to prepare. This is precisely the type of harm Nippon Shinyaku sought to avoid by filing its Motion for Preliminary Injunction almost a year ago. Nippon Shinyaku should not be required to continue expending significant resources on these proceedings after having prevailed at the Federal Circuit.

Third, Sarepta ignores that the parties cannot indefinitely stay the PTAB proceedings. Pursuant to applicable statutory deadlines, the PTAB must issue final written decisions regarding the IPR Petitions within one year from the dates of institution, and, only with a showing of good cause can the USPTO Director extend this date for up to an additional six months. *See* 37 C.F.R. § 42.100(c) ("An *inter partes* review proceeding shall be administered such that pendency before the Board after institution is normally no more than one year. The time can be extended by up to six months for good cause by the Chief Administrative Patent Judge, or adjusted by the Board in the case of joinder."). The earliest institution date for the impermissibly filed IPR Petitions was January 7, 2022, and, thus, absent termination, the PTAB will need to issue the first of its final written decisions by no later than July 7, 2023. If Sarepta chooses to file a petition for certiorari with the Supreme Court and takes the maximum time to file such petition, the petition will not be filed until August 2022 and would not be considered by the Supreme Court until the October term, at the earliest. In these intervening months, Nippon Shinyaku would be required to move

¹ Pursuant to the parties' joint request, the PTAB has stayed the IPR proceedings until the earlier of June 24 or when this Court issues a preliminary injunction. Notably, the PTAB has declined to stay the IPR proceedings indefinitely.

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forward in the PTAB, and, thus, needlessly would be subjected to further irreparable harm, burden, and expense.

Any supposed prejudice that Sarepta claims would result from withdrawing its IPR Petitions now is of its own making—Sarepta filed the IPRs in contravention of a forum selection clause, opposed entry of a preliminary injunction in this Court at every turn—including after the Federal Circuit determined an injunction should be entered (*see* D.I. 94 at 2)—and opposed expedited mandate issuance. That Sarepta now seeks to avoid withdrawing its IPR Petitions so that it is not subject to the one-year statutory bar for refiling should the Supreme Court grant certiorari and overturn the Federal Circuit’s decision is not a basis for further delay of entry of the relief the Federal Circuit has ordered. As the Federal Circuit suggested, the statutory bar’s potential applicability is of Sarepta’s own making. (D.I. 92 at 14 (“[I]t seems possible that if Sarepta had not first filed its IPR petitions, Nippon Shinyaku never would have filed its complaint.”))

Finally, Sarepta wrongly opposes Nippon Shinyaku’s request that the preliminary injunction include a prohibition against Sarepta referencing the IPR Institution Decisions in connection with its invalidity counterclaims/defenses in the instant action. In the absence of such a prohibition, Sarepta improperly would be free to benefit from its breach of contract. Sarepta should be barred from referencing these impermissibly-filed IPR Petitions and any PTAB proceedings pertaining to the same, including the Institution Decisions, in connection with validity issues in the instant action. To allow otherwise would reward Sarepta for its violation of the parties’ bargained-for forum selection clause and only serves to further irreparably harm Nippon Shinyaku.

Sarepta’s Position:

The Federal Circuit remanded this case for entry of a preliminary injunction but did not dictate the scope or form of the injunction. *See, e.g., B. Braun Melsungen AG v. Terumo Med. Corp.*, 778 F.Supp.2d 506, 523 (D. Del. 2011) (district courts have “broad discretion” to determine the appropriate scope of an injunction).

Sarepta proposes entry of an Order that preliminarily enjoins Sarepta from continuing to prosecute the IPR petitions while preserving Sarepta’s right to file a petition for writ of certiorari seeking review of the Federal Circuit’s February 8, 2022 decision. The IPRs are currently stayed by Order of the PTAB at the parties’ joint request. Under Sarepta’s proposal, the IPR petitions would not have to be withdrawn until after the period for seeking certiorari expires if no petition is filed (by August 1, 2022) or the Supreme Court denies certiorari, whichever is earlier. If certiorari is granted, the parties would meet and confer and submit an appropriate proposed Order after the Supreme Court issues its decision on the merits. The parties would not be prohibited from communicating with the PTAB or from requesting that the PTAB maintain or extend the current stay of the IPR proceedings until the certiorari issues have been resolved. The Order would direct the parties to jointly approach the PTAB to seek continued suspension of the IPR proceedings during the period for filing a certiorari petition and through any denial of certiorari if a petition is filed.

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Nippon Shinyaku would not be prejudiced by Sarepta's proposed Order, which does not seek a stay of this case or any delay in discovery or trial. Nor would Nippon Shinyaku be harmed by a continued stay of the IPR proceedings, which would simply maintain the status quo until the certiorari issues have been resolved. The PTAB's final written decisions are not due until January 2023, well after any certiorari petition would be granted or denied. If certiorari is granted, if necessary, good cause would exist to extend the due date for issuance of the final written decisions by up to six months. *See 35 U.S.C. § 316(a)(11); see also Collegium Pharm, Inc. v. Purdue Pharma L.P.*, PGR2018-00048, Paper 57 (PTAB Nov. 19, 2021) (holding that the PTAB has authority to issue a final written decision in a post-grant proceeding even after the extended 18-month period under the statute expires).

Sarepta opposes Nippon Shinyaku's proposed Order, which would require Sarepta to immediately terminate the IPR proceedings and thus preclude Sarepta from pursuing a meaningful petition for writ of certiorari. The Federal Circuit did not—and could not—preclude Sarepta from seeking Supreme Court review of the Federal Circuit's reversal of this Court's decision denying a preliminary injunction. If the IPR petitions are immediately withdrawn, however, Sarepta would be statutorily barred from refiling them after July 14, 2022, before any potential decision by the Supreme Court on a petition for writ of certiorari. 35 U.S.C. § 315(b). Nippon Shinyaku's proposed Order also inappropriately seeks to preclude Sarepta from referencing or relying upon the IPR proceedings, including the PTAB's decisions to institute review, for any purpose concerning the invalidity of Nippon Shinyaku's patents. Nippon Shinyaku did not seek such relief in its preliminary injunction motion and the Federal Circuit did not order it. Nippon Shinyaku can raise any evidentiary objections concerning the IPR proceedings through a motion in limine at the appropriate time in this case.

Counsel for Sarepta are available for a telephone conference at the Court's convenience to discuss these issues.

Counsel for both parties are available should the Court wish to discuss the preliminary injunction.

Respectfully submitted,

/s/ Amy M. Dudash

Amy M. Dudash (DE Bar No. 5741)

cc: All Counsel of Record (via CM/ECF)